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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/384,248	02/06/95	ALIZON M	3495.0008-08

18M2/0415

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EXAMINER	
PARKIN, J	
ART UNIT	**PAPER NUMBER**
1813	

DATE MAILED: 04/15/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/384,248	Alizon et al.
Examiner	**Group Art Unit**
Jeffrey S. Parkin, Ph.D.	1813

☒ Responsive to communication(s) filed on *3/21/97* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *23 and 26-33* is/are pending in the application.

Of the above, claim(s) *26-31* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *23, 32, and 33* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment Filed Pursuant to 37 C.F.R. § 1.129

37 C.F.R. § 1.129(a)

1. Since this application is eligible for the transitional procedure of 37 C.F.R. § 1.129(a), and the fee set forth in 37 C.F.R. § 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 C.F.R. § 1.129(a). Applicants' submission after final filed on March 21, 1997, has been entered. Claims 23, 32, and 33 are currently pending in the instant application while claims 26-31 have been withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. § 112, First Paragraph

3. Claims 23, 32, and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instantly claimed invention is directed toward antibody production methods employing HIV-1 antigens obtained from λ-J19 restriction fragments corresponding to regions of the *gag*, *pol*, and *env* genes, the generation of antibodies against said antigens, and the recovery of said antibodies. As previously set forth, this rejection was based upon the inability of the specification to provide

demonstrative evidence that applicants were in possession of the claimed HIV-1 antigens (i.e., the Gag, Pol, and Env proteins purportedly encoded by the λ-J19 inserts) and that methods for the production and recovery of HIV-1 specific antibodies were adequately described.

Applicants submit the teachings of Wain-Hobson *et al.* (1985) as evidence that the full-length 9193-nucleotide sequence, and corresponding *gag*, *pol*, and *env* coding regions, of the LAV λ-J19 molecular clone were available to the skilled artisan (refer to figure 1, pages 10-12 and table 1, page 12). Applicants further submit that methods for the production of viral antigens encoded from the claimed restriction fragments, as well as methods for the production and recovery of antibodies were readily available in the art (refer to page 3 of paper no. 23 and the teachings of Hurn *et al.*, paper no. 20, respectively). The examiner concurs that the availability of the complete nucleotide sequence of the λ-J19 proviral clone would enable the skilled artisan to produce viral antigens from the claimed restriction fragments. Accordingly, the enablement rejection is hereby withdrawn. However, since this information did not become available to the skilled artisan until January, 1985, and was not disclosed in those applications filed prior to this date (e.g., U.S. serial no. 06/558,109, filed December 05, 1983, and U.K. serial no. 8423659, filed September 19, 1984), priority cannot be extended to those applications filed prior to this date. Accordingly, in view of applicants' submission, the priority date of the instantly claimed invention will be extended to the filing date of **serial no. 06/706,562**, filed **February 28, 1985**.

35 U.S.C. § 102(b)

4. The previous rejection of claim 23 under 35 U.S.C. § 102(b) as being anticipated by Putney *et al.* (1986), is hereby withdrawn in response to applicants' amendment.

5. The previous rejection of claims 23, 32, and 33 under 35 U.S.C. § 102(b) as being anticipated by Luciw *et al.* (1992, US PAT 5,156,949), is hereby withdrawn in response to applicants' amendment.

35 U.S.C. § 103(a)

6. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103© and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

8. Claims 23, 32, and 33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Luciw *et al.* (1992, U.S. PAT 5,156,949). As set forth *supra* in paragraph 3, applicants have been extended priority to February 28, 1985. Luciw *et al.* (1992) receive priority dating to U.S. application serial no. 06/667,501, filed October 31, 1984. Luciw and colleague describe the identification, characterization, and complete nucleotide sequence analysis of a full-length molecular clone of the AIDS virus, designated ARV-2. The precise coding regions of the *gag*, *pol*, and *env* antigens were unequivocally disclosed (refer to Figure 5). The inventors also described the expression, both prokaryotic and eukaryotic, as well as purification of Gag, Pol, and Env (refer to columns 14-16 under the Examples section). It was further reported in column 14 (lines 24-34) that **"The antigenic HIV polypeptide may also be used as immunogens by themselves or joined in other antigens for the production of antisera or monoclonal antibodies which may be used for therapy or diagnosis."** Art-recognized methods were provided for the generation and recovery of immunological reagents (i.e., HIV-1 specific antibodies) directed against these peptides (refer to columns 75-77).

Luciw *et al.* (1992) do not disclose methods for the production of

antibodies directed against antigens expressed specifically from the λ-J19 restriction fragments claimed by applicants. However, Luciw *et al.* (1992) teach that the different HIV-1 isolates described in the prior art are all isolates of the same virus. Specifically it was reported (refer to column 1, fourth paragraph) that "All of these isolates are strains of the same virus, and were later collectively named human immunodeficiency virus (HIV)." Accordingly, one of ordinary skill in the art would readily acknowledge, absent evidence to the contrary, that these different clones all represent obvious variants. Antigens expressed from these different isolates could reasonably be expected to have the same or similar immunogenic and antigenic properties. Accordingly, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to employ restriction fragments corresponding to the *gag*, *pol*, and *env* coding regions obtained from replication competent proviral HIV-1 clones, as disclosed by Luciw et al. (1995), to express HIV-1 viral antigens and employ these antigens in art-recognized methods for the production of HIV-1-specific antibodies. These antibodies would be of obvious clinical and diagnostic import.

9. Claims 23, 32, and 33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hobson *et al.* (1985) in view of Hurn *et al.* (1980). Hobson *et al.* (1985) teach the complete 9193-nucleotide sequence of the lymphadenopathy-associated virus (LAV) (refer to figure 1, pages 10-12). This sequence was derived from a phage λ-J19 proviral clone that appears to be identical to that disclosed by applicants. The location, size, and coding potential of several viral genes including *gag*, *pol*, and *env* were identified. This

teaching does not recite the precise restriction fragments claimed by applicants or methods for the generation of immunological reagents.

Hurn *et al.* (1980) provide art-recognized methods for the generation of immunological reagents (e.g., polyclonal and monoclonal antibodies). The authors describe, *inter alia*, immunogen preparation, adjuvant selection, immunization routes and dosing, hybridoma selection and preparation, and antibody isolation and purification. This teaching does not disclose any HIV restriction fragments.

However, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to employ λ-J19 restriction fragments corresponding to the *gag*, *pol*, and *env* coding regions as disclosed by Hobson *et al.* (1985), to express HIV-1 viral antigens and employ these antigens in art-recognized methods for the production of HIV-1-specific antibodies, as taught by Hurn *et al.* (1980). These antibodies would be of obvious clinical and diagnostic import.

Correspondence

10. Correspondence related to this application may be submitted to Group 1813 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Group 1813 is **(703) 305-7939. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.**

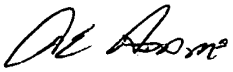
11. Any inquiry concerning this communication should be directed to **Jeffrey S. Parkin, Ph.D.**, whose telephone number is **(703) 308-2227**. The examiner can normally be reached Monday through Friday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail

service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, **Donald E. Adams, Ph.D.**, can be reached at **(703) 308-0570**. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1813 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1813

April 11, 1997



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